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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,263	04/10/2006	Motoyuki Kataoka	KATAOKA3	8893

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EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

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06/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,263	KATAOKA ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11,16-18 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,16-18 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. In the amendment filed 04/06/2009 Applicant amended claims 10, 11 and 18 and added the new claims 22 and 23. Claims 10, 11, 16-18 and 20-23 are pending and under examination.

Specification

2. Claim 10 is objected to because of the following informalities: in line 3 of the claim, the word "granulocyte" is misspelled.

Claims 11 and 18 are objected to because of the following informalities: in line 5 of claims 11 and 18 the word “G-CSF” should not be in parenthesis. Also in claim 18 the word ”therefore” is misspelled.

Appropriate correction is required.

New and Maintained claim rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is unclear what the meaning of the

phrase "said effective amount is based on the G-CSF itself" is. As such, the metes and bounds of the claims could not be established.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10 and 20-21 remain and the new claims 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Shishido et al. (Nichijinshi, 33, 973-981, 1991) cited in the previous Office actions) for the reasons of record.

Shishido et al treated end-stage renal failure patients with human recombinant G-CSF and found it an effective and safe therapeutic agent for neutropenia and neutrophil dysfunction in patients with renal failure (Abstract). Clearly Shishido et al. teach a method of treatment of renal failure (a renal disease or **nephropathy**). Moreover, it is considered that end-stage renal failure is accompanied by necrosis, and thus the method of treatment of Shishido et al. inherently addresses the limitations of claims 18, 20-23 also. Therefore, all the consequences of the G-CSF treatment were necessarily (inherently) achieved and thus the claims are anticipated by Shishido et al. The position

of the Office is that the therapeutic agent's properties are inherent to its function and the activity of the agent does not stop because the use was not an intended use. Once the G-CSF is administered to a nephropatic patient, the drug would exert its action irrespective to the etiology of the disease.

On page 6-7 of the Remarks Applicant argues that the instant Invention is novel over Shishido because Shishido et al. have not intended their treatment for diabetic or atherosclerotic nephropathy. The arguments were carefully considered but not found persuasive because, as iterated above, Shishido et al. are treating nephropathies. Once the treatment has been administered, the G-CSF would exert its effects, irrespective of the original intent of the practitioner. Thus, by performing the method of Shishido et al. a skilled artisan would also practice the current invention

Claims 10 and 20-21 remain and the new claims 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Fukuda et al. (U.S. Pub. 20040019184-cited in the previous Office actions) for reasons of record.

As presented previously, Fukuda et al. teaches treating renal disease by administering G-CSF to patients for whom this remedy is indicated.

On page 8-9 of the Remarks Applicant argues that Fukuda does not disclose treating diabetic nephropathy or atherosclerotic nephropathy or that the administration has to be a combined Hepatocyte Growth Factor- G-CSF treatment. The arguments were carefully considered but not found persuasive because Fukuda does teach treatment of renal diseases with G-CSF. As stated supra, the position of the Office is

that the therapeutic agent's properties are inherent to its function and the activity of the agent does not stop because the use was not an intended use. That is especially true when no dosage is claimed and there is no indication from the Specification that dosages presented by Fukuda would be ineffective for the regeneration/reparation of renal tissue. Regarding the combined administration, Fukuda et al. clearly states that G-CSF and HGF can be prepared and administered as a single preparation or alternatively, they can be prepared separately, and administered on different occasions ([0057]). At least in the instance that the G-CSF is administered separately, a practitioner would have performed the method of the instant Application. Further, there are no limitations in the claims to exclude combined administration. Moreover, one of the embodiments of the instant Application clearly is culturing and regenerating cells from the renal tissue in vitro. As such other growth factors would be present in order to have a viable tissue culture in vitro.

Applicant also argues on page 8 that the interpretation of the recitation "G-CSF of the present invention" in paragraph [0017] of Fukuda must be understood to mean "G-CSF in combination with HGF of the present [Fukuda] invention". The arguments were carefully considered but not found persuasive because Fukuda et al. clearly is aware and envisioned a treatment using G-CSF:

> [0014] In patients with obstructive arteriosclerosis, administration of human G-CSF prior to treatment with intramuscular transplantation of bone marrow cells can be expected to increase the frequency of hematopoietic stem cells in the bone marrow. Thus, the number of bone marrow punctures for collecting bone marrow cells can be reduced, and the burden on the patient can be reduced. On this occasion, the burden on the patient and the medical staff can be further reduced by

obtaining hematopoietic stem cells for transplantation from the peripheral blood. Furthermore, hematopoietic stem cells in the peripheral blood have been shown to contribute to vasculogenesis, so that the increase of hematopoietic stem cells in the peripheral blood induced by the administration of human G-CSF is speculated to promote vasculogenesis. Hence, the mere administration of human G-CSF to patients can be expected to treat obstructive arteriosclerosis. This treatment for obstructive arteriosclerosis by the administration of human G-CSF will clearly reduce the burden on the patient and the medical staff markedly in that it obviates the need for collection and transplantation of hematopoietic stem cells.

Further, the addition of HGF is for the additive effects and in no way precludes the use of the G-CSF only ([0018]). Moreover, as presented supra, it is clearly stated that the G-CSF administration would treat atherosclerosis and, according to the inherent properties of G-CSF, atherosclerotic nephropathy is comprised. Finally, the claims do not preclude administration of other drugs, including HGF.

Thus the teachings of Fukuda anticipate the claims 10 and 20-23 of the instant Application.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 11 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shishido et al. (Nichijinshi, 33, 973-981, 1991) in view of Shi et al. (U.S. Pub No. 20020012966).

The teachings of Shishido et al. were presented above. They are silent about specifically treating diabetic or atherosclerotic nephropathies.

Shi et al. teach novel secreted proteins with therapeutic properties (abstract). Some of the proteins may be used to treat atheroembolic renal failure and diabetic nephropathy ([644]). The therapeutic proteins can be used in conjunction with growth factors such as G-CSF.

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have tried the use of the G-CSF as taught by Shishido et al.

toe treat diabetic nephropathy as taught by Shi et al. with a reasonable expectation of success, since Shishido et al. used G-SCF in nephropathies and Shi et al. suggested the used of G-CSF (in combinations) for treatment of diabetic nephropathy.

A person of ordinary skill in the art is always motivated to pursue the known options within her or his technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense, as eloquently expressed in the Supreme Court decision in KSR International Co. v. Teleflex Inc., 550 US, 82 USPQ2d 1385 (2007).

9. Claims 11 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al. (U.S. Pub. 20040019184-cited in the previous Office actions) in view of Shi et al. (U.S. Pub No. 20020012966).

The teachings of Fukuda et al. were presented above. They are silent about specifically treating diabetic or atherosclerotic nephropathies.

Shi et al. teach novel secreted proteins with therapeutic properties (abstract). Some of the proteins may be used to treat atheroembolic renal failure and diabetic nephropathy ([644]). The therapeutic proteins can be used in conjunction with growth factors such as G-CSF ([310]).

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have tried the use of the G-CSF as taught by Fukuda et al. et al. to treat diabetic nephropathy as taught by Shi et al. with a reasonable expectation of success, since Fukuda et al. used G-SCF in nephropathies and Shi et al. suggested the used of G-CSF (in combinations) for treatment of diabetic nephropathy.

A person of ordinary skill in the art is always motivated to pursue the known options within her or his technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense, as eloquently expressed in the Supreme Court decision in KSR International Co. v. Teleflex Inc., 550 US, 82 USPQ2d 1385 (2007).

Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/
Primary Examiner, Art Unit 1647